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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,962	12/03/2003	David Ernest Hartley	PA-5356-RFB	4369
9896 7590 06/06/2007 COOK GROUP PATENT OFFICE P.O. BOX 2269 BLOOMINGTON, IN 47402			EXAMINER DOWE, KATHERINE MARIE	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 06/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/726,962

Applicant(s)

HARTLEY ET AL.

Examiner

Katherine M. Dowe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 19-23 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 19-23 and 25-27 is/are rejected.
- 7) ☒ Claim(s) 25-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is a complete response to the amendment filed 5/9/2007.
Examiner acknowledges cancelled claims 6-18 and 24 and amended claims 19, 25, and 27. Thus, claims 1-5, 19-23, and 25-27 are currently pending.

Election/Restrictions

2. Applicant's election of Invention I (claims 1-5) and Invention II (claims 19-27) in the reply filed on 5/9/2007 is acknowledged. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/9/2007.

Claim Objections

3. Claims 25-27 are objected to because of the following informalities: The claims are dependent on claim 24, which has been cancelled. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Cook et al. (US 7,175,652). Cook et al. disclose a tubular prosthesis (10) that is capable of being fastened around the aortic heart valve and extended into the descending aorta. The prosthesis comprises a distal end including an internal self-expanding stent (40) with barbs (36) and an extending uncovered self-expanding stent (18). Furthermore, the prosthesis may be bifurcated (Fig 3) and thus capable of connecting side branches or other major arteries.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 7,175,652), as applied to claim 1 above, in view of Ivancev et al. (US 6,773,457). Cook et al. disclose the invention substantially as claimed including a

tubular prosthesis (10) comprising a distal end including an internal self-expanding stent (40) with barbs (36) and an extending uncovered self-expanding stent (18). However, Cook et al. do not disclose the prosthesis is formed from a corrugated material. Ivancev et al. disclose a similar prosthesis (1) that may be deployed in the aorta (col 4, ln 60-67). Ivancev et al. teach the prosthesis should be corrugated to promote setting of the graft in a curved shape and promote the flexibility of the graft (col 5, ln 10-12).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cook et al. such that the prosthesis was formed from a corrugated material such that it may be more flexible and easier to place in the aorta.

9. Claims 19, 20, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chobotov et al. (US 2002/0151953) in view of Ivancev et al. (US 6,773,457). Regarding claims 19-20 and 25, Chobotov et al. disclose the invention substantially as claimed including a prosthesis (11) mounted on a deployment device (Fig 1) comprising a deployment catheter (53) coaxially around a central catheter (207) with a distal end designed to be inserted in the descending aorta (para 0074). The distal end of the central catheter comprises a nose cone (44), which uses a trigger wire (24) to retain the distal end of the prosthesis (para 0085). However, Chobotov et al. do not disclose the prosthesis is everted during deployment. Ivancev et al. disclose a similar method for inserting a prosthesis (Fig 1) in the aorta (col 2, ln 24-29). Ivancev et al. teach a deployment method to insert the prosthesis in the ascending and descending

aorta in which the ascending portion of the graft is inverted down into the descending portion of the graft initially. The inverted device is inserted into the descending aorta (Fig 4), fixed in place, then the ascending portion of the graft is inverted and placed in the ascending aorta (Fig 5). Thus, the surgeon is able to conduct the surgery more quickly such that the patient will be able to reestablish circulation faster (col 2, ln 29-33; col 6, ln 31-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Chobotov et al. such that the prosthesis was everted such that a folded central portion was attached to the deployment device to simplify the deployment method of deploying the prosthesis in the ascending and descending aorta, thereby reducing the surgical time and thus the risk for the patient.

Regarding claim 23, Chobotov et al. additionally do not disclose the prosthesis is formed from a corrugated material. Ivancev et al. disclose a similar prosthesis (1) that may be deployed in the aorta (col 4, ln 60-67). Ivancev et al. teach the prosthesis should be corrugated to promote setting of the graft in a curved shape and promote the flexibility of the graft (col 5, ln 10-12). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Chobotov et al. such that the prosthesis was formed from a corrugated material such that it may be more flexible and easier to place in the aorta.

10. Claims 21, 22, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chobotov et al. (US 2002/0151953) and Ivancev et al. (US

6,773,457), as applied to claim 19 above, in view of Cook et al. (US 7,175,652).

Chobotov et al. disclose the invention substantially as claimed including a prosthesis (11) mounted on a deployment device (Fig 1) comprising a deployment catheter (53) coaxially around a central catheter (207) with a distal end designed to be inserted in the descending aorta (para 0074). The distal end of the central catheter comprises a nose cone (44), which uses a trigger wire (24) to retain the distal end of the prosthesis (para 0085). However, Chobotov et al. do not disclose the prosthesis is everted during deployment. Ivancev et al. disclose a similar method for inserting a prosthesis (Fig 1) in the aorta (col 2, ln 24-29). Ivancev et al. teach a deployment method to insert the prosthesis in the ascending and descending aorta in which the ascending portion of the graft is inverted down into the descending portion of the graft initially. The inverted device is inserted into the descending aorta (Fig 4), fixed in place, then the ascending portion of the graft is inverted and placed in the ascending aorta (Fig 5). Thus, the surgeon is able to conduct the surgery more quickly such that the patient will be able to reestablish circulation faster (col 2, ln 29-33; col 6, ln 31-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Chobotov et al. such that the prosthesis was everted such that a folded central portion was attached to the deployment device to simplify the deployment method of deploying the prosthesis in the ascending and descending aorta, thereby reducing the surgical time and thus the risk for the patient.

Furthermore, Chobotov et al. disclose the prosthesis comprises an uncovered self-expanding stent (33) extending from the distal end of the prosthesis. Additionally,

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the prosthesis itself is structurally supported by inflatable cuffs (30 and 28) and inflatable channels (284). However, Chobotov et al. do not disclose the prosthesis comprises an internal self-expanding stent or that the uncovered stent comprises barbs. Cook et al. disclose a similar prosthesis that may be placed in the aorta. Cook et al. teach the prosthesis may be supported by an internal self-expanding stent (40) with barbs (36) and an extending uncovered self-expanding stent (18). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Chobotov et al. such that the uncovered stent comprised barbs and such that the prosthesis comprised an internal self-expanding stent in place of the inflatable cuffs and channels. Thus the prosthesis would have a more stable structure and could be better anchored and secured upon delivery. Additionally, regarding claims 26 and 27, it is obvious that if the prosthesis comprised an internal stent and barbs as shown above, the trigger wire, which retains the entire prosthesis in Chobotov et al., would also retain the internal stent and barbs since it is inherent that if the outer prosthesis and outer uncovered stent are in a contracted condition, the internal stent and internal barbs must also be in a contracted condition.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Roy (US 7,074,235).

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571) 272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
May 23, 2007



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER